K112251

JAN 25 2012

5. 510(k) Summary

5.1 Submitter

Swissmeda AG
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5.2 Official Correspondent

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5.3 Date of Submission

07/01/2011

5.4 Device Information

Trade name:	Swissmeda Dental Planning System
Version:	2.4
Common Name:	Dental Planning System
Device Class:	Class II
Classification Name:	System, Image Processing System, Radiology
Regulation Description:	Picture archiving and communications system
Classification Number:	21 CFR 892.2050
Product Code:	LLZ

5.5 Predicate Device

Manufacturer:	IVS Solutions AG, Annaberger Strasse 240, Chemnitz, Germany
Trade Name:	coDiagnostiX®
510(k) Number:	K071636
Regulation Number:	892.2050
Product Code:	LLZ

5.6 Device Description

Swissmeda Dental Planning System is a stand-alone software device.

It is a Windows® based software application for the visualization of imaging information of the patient's mandible/maxilla region. It is intended to be used for diagnostics and a precise and reproducible pre-operative planning of dental implants and surgical treatment by aid qualified dental professionals.

Imaging data from medical scanners such as CT or DVT scanners (DICOM Standard) will be read in. The software calculates a volumetric (3 dimensional) data set which will be displayed in different windows: One shows the data as volume data where every voxel of the data set is shown with a grey value that defines the density of the bone substance. Three other windows show a slice through the 3d data set as a flat image. During a planning session the data can be stored to pause the planning session and can be reloaded to continue the planning session.

By inspection of the 3d information of the bone the dental professional can deduct hints where to place what kind of implants. To support planning the user is enabled to predefine a dental occlusion spline and an occlusion plane. He can select implants from a given implant catalog and insert them into the 3d data set at the predefined position given by the dental spline and the tooth number. The implant catalog contains real geometry of several implants from several different vendors. Swissmeda Dental Planning System has no limitations regarding material or surface types of implants.

For each patient several versions of the plan can be created, restored and exported each time.

The final planning data may be exported from Swissmeda Dental Planning System and used as input data for a special drilling device from company Georg Schick Dental GmbH* for manufacturing drilling templates in a laboratory environment. The drilling template is then used in direct contact with the patient to realize the implant planning during the surgery.

* The drilling device from company Georg Schick Dental GmbH is a high accuracy positioning table, which also can be used like conventional rotary tables for purposes of model making.

5.7 Intended Use

Swissmeda Dental Planning System is intended for use by qualified dental professionals for Windows® based diagnostics and implant planning.
The software is an interface for imaging data that originates from medical scanners such as CT or DVT scanners and it is also a pre-operative software for simulation and

evaluation of dental implant placement in the patient's mandible/maxilla and for surgical treatment options.

Swissmeda Implant Planning System is not intended to be used in direct contact with the patient nor is it intended to be used with life sustaining devices.
The planning data may be exported from Swissmeda Dental Planning System and used as input data for the mentioned drilling device for manufacturing drilling templates in a laboratory environment. The drilling template is then used in direct contact with the patient to realize the implant planning.

5.8 Safety Information

Swissmeda Dental Planning System is a stand-alone software device that handles digital medical images. The device does not contact the patient, nor does it control any life sustaining devices.
All potential hazards have been identified and analyzed. The result of this analysis indicates that the device is of moderate level of concern as per "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

5.9 Substantial Equivalence

The Swissmeda Dental Planning System is substantially equivalent to and performs as good as the predicate device coDiagnostiX® (K071636) based on the equivalence of the intended use, similar features and technological characteristics. Any differences between the devices do not raise new issues of safety and effectiveness.

5.10 Conclusion

Swissmeda Dental Planning System considered to be substantially equivalent to the coDiagnostiX® System.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JAN 25 2012

Dr. Jorg Danzberg
Chief Executive Officer
Swissmeda AG
Technoparkstrase 1
8005 ZURICH
SWITZERLAND

Re: K112251
Trade/Device Name: Swissmeda Dental Planning System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 6, 2011
Received: December 19, 2011

Dear Dr. Danzberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112251

Device Name: Swissmeda Dental Planning System

Indications for Use:

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Swissmeda Implant Planning System is not intended to be used in direct contact with the patient nor is it intended to be used with life sustaining devices.

The planning data may be exported from Swissmeda Dental Planning System and used as input data for a special drilling device from company Georg Schick for manufacturing drilling templates in a laboratory environment. The drilling template is then used in direct contact with the patient to realize the implant planning.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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